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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,690	12/08/2003	Michael Miller	1194.1101101	5711

7590 10/13/2005

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/730,690	Applicant(s) MILLER, MICHAEL	
	Examiner Jaworski Francis J.	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/19, 3/30, 9/3/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>219,330,90304</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 – 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant is claiming a tubular insertable apparatus in the base claim preambles whereas the extracorporeal element is claimed as apart from this apparatus. Additionally, since a unit is definable either a whole or a portion of a whole, in the trivial sense the ultrasound receiver processing and display console is always found at least partly extracorporeally hence it is unclear whether a transducer portion is being claimed here. For purposes of examination on the merits the Examiner is interpreting the claim as pertaining to the combination of a device and a device-locator system, where at least some of the system in toto is extracorporeally located.

Dependent claims variously inherit the defect.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daikuzono (US5623940) or Shturman (US5331947), in either case further in view of Lipscher et al (US5785051, of record). In the case of the Daikuzono et al catheter, first balloon 1 and second (positioning) balloon 2 are filled with transmissive fluid such that

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the ultrasound positioning imager 92 described for example in col. 13 lines 47-58 may be coupled to the prostatic or esophageal/bronchial environment (col13 lines 62-66). In the case of Shturman, transbronchial ultrasound positioning imaging may be accomplished using first and second catheter balloons 96 and 30, the latter being filled with acoustically transmissive fluid (Fig. 16). It would in either case have been obvious in view of Lipscher et al of record to effect ultrasound location monitoring by at least one external ultrasound transducer and a signal processing unit extracorporeally placed. Lipscher otherwise teaches features associated with an end-tapered balloon cuff ETT catheter and steps associated with correct positional placement of an ETT cuff within the airway.

Abrams (US4671295) is cited for its Fig. 4 dual cuff tracheal tube and contact-type ultrasoundr sensing system mounted thereon.

Roth et al (US5207672) teaches a dual balloon catheter in Fig. 6 including paired ultrasound positioning transducers 10, 12 and is stated to be applicable to tumor tissue treatment throughout the body.

Mesallum (US6689062 B1) is directed to transesophageal ultrasound imaging through ultrasound transmissive coupling balloon 24.

Slepian (US5662609) is directed to a multi-balloon catheter for bronchial tumor therapy (col. 7 line 65) which contains an ultrasound therapeutic transducer.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj 09282005



Francis J. Jaworski
Primary Examiner